K001468

OCT 2 3 2000

# 510(k) Summary - ELECSYS® CA 15-3 on ELECSYS® 2010 and 1010 Immunoassay Analyzers

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**Introduction**

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

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**Submitter name, address, contact**

Roche Diagnostics Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 576 3723

Contact person: Priscilla A Hamill

Date prepared: February 7, 2000

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**Device Name**

Proprietary name: ELECSYS® CA 15-3 Test System

Common name: CA 15-3 Test

Classification name: System, Test, Tumor Marker, Monitoring, Breast

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**Device description**

The ELECSYS® CA 15-3 Test System a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection.

Results are determined using a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve provided with the reagent bar code.

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## 510(k) Summary - ELECSYS® CA 15-3 on ELECSYS® 2010 and 1010 Immunoassay Analyzers, continued

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|---|---|
| **Intended use** | For the quantitative determination of CA 15-3 in human serum and plasma. |
| **Indication for use** | The determination of CA 15-3 is used in the management of patients with breast cancer. |
| **Substantial equivalence** | The ELECSYS CA 15-3 test is equivalent to other devices legally marketed in the United States. We claim equivalence to the AxSYM® CA 15-3 test marketed by Abbott Laboratories (K963926) and the Immuno 1™ System CA 15-3 Assay marketed by Bayer (K964703). |

**Substantial equivalence - similarities**

The following table compares the ELECSYS® CA 15-3, with the predicate devices.

| Feature | New Device ELECSYS CA 15-3 | Predicate Device AxSYM CA 15-3 | Predicate Device Bayer Immuno 1 |
|---|---|---|---|
| Intended use | For the quantitative determination of CA 15-3 | For the quantitative determination of CA 15-3 | For the quantitative determination of CA 15-3 |
| Indication for use | To aid in the management of breast cancer patients. In conjunction with other clinical and diagnostic procedures, serial testing with the CA 15-3 assay is an aid in the early detection of recurrence in previously treated stage II and III breast cancer patients and for monitoring response to therapy in metastatic breast cancer patients. | To aid in the management of Stage II and III breast cancer patients. | Monitoring the course of disease and therapy in metastatic breast cancer patients, and for detection of recurrence in previously treated Stage II, with greater than 2 positive lymph nodes, or Stage III breast cancer patients |
| Analytical specificity | Based on monoclonal 115D8 and DF3 antibodies available from Centocor | Based on monoclonal 115D8 and Df3 monoclonal antibodies | Based on monoclonal 115D8 and Df3 monoclonal antibodies from Centocor. |
| Sample type | Human serum and plasma | Human serum and plasma | Human serum |
| Traceability | Calibrated against Roche Enzymun-Test CA 15-3 method which in turn was calibrated against the Centocor CA 15-3 RIA assay. | Abbott reference preparation prepared from DF3 antigen from Centocor | DF3 antigen from Centocor used in calibrators |

## 510(k) Summary - ELECSYS® CA 15-3 on ELECSYS® 2010 and 1010 Immunoassay Analyzers, continued

**Substantial equivalence – differences**

The following table compares the ELECSYS® CA 15-3, with the predicate device.

| Feature | New Device ELECSYS CA 15-3 | Predicate Device AxSYM CA 15-3 | Predicate Device Bayer Immuno 1 CA 15-3 |
|---|---|---|---|
| Assay principle | Electrochemilumines-cence immunoassay (ECLIA) employing the sandwich principle | Microparticle Enzyme Immunoassay (MEIA) technology | • Sandwich Magnetic Separation Assay (MSA) |
| Instrument | ELECSYS® 2010 and 1010 Immunoassay Analyzers | AxSYM System | Bayer Immuno 1 Immunoassay System |
| Measuring range | 1.00-300 U/mL | 0.3-250 U/mL | 0.2-200 U/mL |
| Expected values | <25 for 95% of subjects | < 31.3 for 99.1% of 698 healthy females | < 35.9 (97.5$^{th}$ percentile) |

**Substantial equivalence – performance characteristics**

The performance characteristics of the ELECSYS CA 15-3 and the predicate device are compared in the table below.

| Feature | New Device ELECSYS CA 15-3 | Predicate Device AxSYM CA 15-3 | Predicate Device Bayer Immuno 1 CA 15-3 |
|---|---|---|---|
| Within-Run precision (%CV) | • 3.0% at 27.4 U/mL<br>• 4.3% at 41.4 U/mL<br>• 4.5% at 122.8 U/mL<br>• 3.2% at 20.9 U/mL<br>• 3.8% a5 61.6 U/mL | • 3.5-5.4% Panel 1 (33.5-38.1 U/mL)<br>• 5.1-6.7% Panel 2 (129.7-158.5 U/mL)<br>• 2.8-3.5% Panel 3 (12.9-14.5 U/mL<br>• 3.3-3.9% Panel 4 (87.2-104.8 U/mL<br>• 4.7-5.5% Panel 5 (130.5-160.8 U/mL | • 3.4% at 13.5 U/mL<br>• 2.4% at 35.0 U/mL<br>• 1.6% at 33.2 U/mL<br>• 1.8% at 13.3 U/mL<br>• 2.1% at 26.0 U/mL<br>• 2.4% at 50.7 U/mL<br>• 1.9% at 102.3<br>• 1.3% at 190.9 U/mL |
| Total precision (%CV) | • 3.8% at 27.4 U/mL<br>• 6.7% at 41.4 U/mL<br>• 5.2% at 122.8 U/mL<br>• 3.9% at 20.9 U/mL<br>• 4.7% a5 61.6 U/mL | • 4.5-8.6% Panel 1 (33.5-38.1 U/mL)<br>• 6.0-7.1% Panel 2 (129.7-158.5 U/mL)<br>• 3.8-5.2% Panel 3 (12.9-14.5 U/mL<br>• 5.4-6.0% Panel 4 (87.2-104.8 U/mL<br>• 6.9-7.2% Panel 5 (130.5-160.8 U/mL | • 4.0% at 13.5 U/mL<br>• 3.1% at 35.0 U/mL<br>• 3.3% at 33.2 U/mL<br>• 3.5% at 13.3 U/mL<br>• 3.7% at 26.0 U/mL<br>• 3.7% at 50.7 U/mL<br>• 3.4% at 102.3<br>• 3.0% at 190.9 U/mL |

| | | | |
|---|---|---|---|
| Analytical sensitivity | 1.00 U/mL | 0.30 U/mL | 0.2 U/mL |
| Limitations | • No interference from icterus up to 66 mg/dL<br>• No interference from hemolysis up to 2.0 g/dL<br>• No interference from Intralipid up to 1500 mg/dL triglyceride<br>• No interference from biotin up to 60 ng/mL<br>• No interference from rheumatoid factor up to 1500 U/mL<br>• No high dose hook effect up to 20,000 U/mL | • No interference from bilirubin up to 20 mg/dL<br>• No interference from hemoglobin up to 600 mg/dL<br>• No interference from triglyceride up to 3000 mg/dL<br>• No interference from IgG from 250-2900 mg/dL<br>• No interference from Total Protein from 3-12 gm/dL | • No interference from bilirubin up to 25 mg/dL<br>• No interference from hemoglobin up to 1 g/dL<br>• No interference from triglycerides up to 900 mg/dL<br>• No interference from Immunoglobulin up to 5.3 g/dL<br>• No interference from heparin up to 0.15 mg/mL<br>• No interference from albumin up to 6.5 g/dL<br>• No hook effect up to 28,500 U/mL |
| On-board stability | • Elecsys® 2010: 4 weeks<br>• Elecsys® 1010: 3 weeks (stored alternately in refrigerator and analyzer at ambient temperature 20-25 C) Up to 20 hr. opened in total | A total of 112 cumulative hours | 30 days |

| | | | |
|---|---|---|---|
| Calibration frequency | • Elecsys® 2010: Once per reagent kit and after 3 days when using the same reagent kit<br>• Elecsys® 1010 Once per reagent kit and after 3 days when using the same reagent kit (ambient temp 20-32 C)<br>• Controls out of range (both systems) | • With a new lot number, or<br>• Controls out of range | • With a change in test component<br>• Every 60 days |
| Accuracy | Method comparison of Elecsys® CA 15-3 (Y) to AxSYM CA 15-3 (X):<br>Y = 1.099 X + 0.479<br>(n = 1170) | | |

DEPARTMENT OF HEALTH & HUMAN SERVICES

OCT 2 3 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Priscilla A. Hamill
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K001468
Trade Name: Roche Diagnostics ELECSYS® CA 15-3 Test System
Regulatory Class: II
Product Code: MOI
Dated: September 13, 2000
Received: September 14, 2000

Dear Ms. Hamill:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# INDICATIONS FOR USE STATEMENT

510(k) Number (if known): N/A

Device Name: ELECSYS® CA 15-3 Test System

Indications For Use: For the quantitative determination of CA 15-3 in human serum and plasma to aid in the management of breast cancer patients. In conjunction with other clinical and diagnostic procedures, serial testing with the CA 15-3 assay is an aid

- In the early detection of recurrence in previously treated Stage II and III breast cancer patients
- For monitoring response to therapy in metastatic breast cancer patients.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys® 1010 and 2010 Immunoassay Analyzers.

Peter E. Maxim

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001468

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)